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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,630	BOLTON ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The **examiner** of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michail Belyavskyi, Group Art Unit 1644, Technology Center 1600

Claims 1-19 are pending.

Applicant's election without traverse of oxidative stress and ultraviolet radiation as species of stressors in the reply filed on 09/08/04 is acknowledged.

Claims 1-19 drawn to a method of treating ulcers in a mammalian patient to accelerate the healing thereof and a process of increasing the expression of TGF-β1 from cells in a mammalian , each comprising administering stressed mammalian blood cells wherein stressors are oxidative conditions, ultraviolet radiation and heat are under consideration in the instant application.

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on 12/05/2000. It is noted, however, that applicant has not filed a copy of the 2,327630 application as required by 35 U.S.C. 119(b).

3. The disclosure is objected to because of the following informalities: there is no description of Figures 1 and 2 in the "Brief Description of the Drawings" section in the instant application.

Appropriate correction is required.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Dependent claims 9 recites "temperature stressor". There is insufficient antecedent basis for this limitation in the claims, since base Claim 5 does not recite " temperature stressor".

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of increasing the expression of TGF-β1 from cells in mammalian patients comprising administering to the patient an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation does not reasonably provide **enablement** for (i) alleviating in the patient the symptoms of *any* disorder associated with TGF-β1 deficiency, claimed in claim 1; and (ii) a method for treating ulcers in a mammalian in a patient comprising administering to the patient an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification only discloses a contact hypersensitivity (CHS) test on Balb/c mice (see Example 1 in particular) and the increase in the expression levels for TGF-β1 in human patients with moderate to severe psoriasis after injection to said patients stressed blood cells (see

example 2 in particular) . However, it is noted that there are no data on the change in the ear thickness in treated and control mice.

The specification does not adequately teach how to effectively alleviate *any* disorder associated with TGF-β1 deficiency and to treat any ulcers in a patient, by administering an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation. Moreover, no animals models were used to study the effectively of alleviating *any* disorder associated with TGF-β1 deficiency or treatment of ulcers in a patient, by administering an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation. Since there is no animal model studies and data in the specification to show the effectively of alleviating *any* disorder associated with TGF-β1 deficiency or treatment ulcers in a patient comprising administering to the patient an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation it is unpredictable how to correlate a contact hypersensitivity (CHS) test on Balb/c mice and the increase in the expression levels for TGF-β1 with claimed *in vivo* use. Moreover, the is no indication or teaching in the Specification of *any* disorder associated with TGF-β1 deficiency . Moreover, Applicant acknowledge that the precise mechanism of the action of TGF-β1 is not understood (see page 2, line 11 in particular). Feldman et al (Transplant. Proc. 1998, 30, 4126-4127) teach that "while it is not difficult to study the pathogenesis of animal models of disease, there are multiple constraints on analyses of the pathogenesis of human disease, leading to interesting dilemmas such as how much can we rely on and extrapolate from animal models in disease". In addition, Cochlovius et al (Modern Drug Discovery, 2003, pages 33-38) teach that in contrast to in vitro models, and partly animal-human xenograft systems, tissue cells in vivo seems to express molecules for defense against cellular immune systems as well as against complement. Although these defense mechanisms are still poorly understood, they provide some hints as to why many potential therapeutics perform marvelously in vitro but a fairly high portion of them still fail in vivo. Feldman et al ., further teach that in a chronic immune-driven inflammatory response there are a number of pathways that become engaged and effective therapy in immune inflammatory diseases such as rheumatoid arthritis, will come from therapy aimed at several points in the disease pathway.

Since the method of treating ulcers in a patient, by administering an effective amount of stressed mammalian blood cells can be species- and model-dependent (see Van Noort et al. International Review of Cytology, 1998, v.178, pages 127-204, Table III in particular) , it is not clear that reliance on the contact hypersensitivity (CHS) test on Balb/c mice and the increasing in the expression levels for TGF-β1 in human patients with moderate to severe psoriasis after injection to said patients stressed blood cells accurately reflects the relative mammal and human efficacy of the claimed therapeutic strategy. The specification does not teach how to extrapolate data obtained from the above discussed studies to the development of effective *in vivo* mammalian including human therapeutic treatment, commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of a method of treating ulcers in a patient, by administering an effective amount of stressed

mammalian blood cells. Thus in the absence of working examples or detailed guidance in the specification, the intended uses of any pharmaceutical composition comprising stressed mammalian blood cells are fraught with uncertainties.

Moreover, an effective protocol for a method of treating ulcers in a patient, is subject to a number of factors which enter the picture beyond simply the administration to the subject an effective amount of stressed mammalian blood cells. The disclosure of a contact hypersensitivity (CHS) test on Balb/c mice and the increase in the expression levels for TGF-β1 in human patients with moderate to severe psoriasis after injection to said patients stressed blood cells cannot alone support the predictability of a method of treatment or prophylaxis of any inflammatory disease in a patient by administration to the subject an effective amount of stressed mammalian blood cells. Van Noort et al. (International Review of Cytology, 1998) indicate factors that effect immune response such as genetic, environmental and hormonal (Page 176, Paragraph 3). The ability of a host to enhance an immune response will vary depending upon factors such as the condition of the host and burden of disease.

The specification does not provide sufficient teaching as to how it can be assessed that alleviating of *any* disorder associated with TGF-β1 deficiency were alleviating or any ulcers were treated in a mammalian after the administration of a therapeutically effective amount of stressed mammalian blood cells.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed alleviating in the patient the symptoms of *any* disorder associated with TGF-β1 deficiency, or a method for treating ulcers in a mammalian in a patient both comprising administering to the patient an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. Also an issue is that the incorporation of essential material in the specification by reference to PCT/CA00/00433 on page 11, line 13 for a contact hypersensitivity test according to approved animal experimentation procedures is improper because an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, see MPEP 608.01(p),. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,980,954 or WO 98/07436.

US Patent '954 teaches a method of treating an inflammatory disease including psoriasis disease in a mammalian patient comprises administering to the patient stressed mammalian blood cells (see the entire document, column 1, and overlapping columns 7 –8 in particular) . The US Patent '954 teaches that stress blood cells have been extracting from the patient an aliquot of blood of volume, contacting the aliquot of blood, extracorporeally subject to at both oxidative conditions, ultraviolet radiation and heat stress simultaneously. (see column 6, in particular). The US Patent '954 teaches that oxidative environment, such as a mixture of ozone, wherein an ozone content from about 0.5 to about 100 μg/ml and oxygen bubbled through the blood aliquot, from about 0.5 to 60 min (see overlapping columns 7-8 and Claim 5 in

particular). The US Patent '954 teaches that the temperature stressor is in a range from about 40 to about 55° C (see column 7 and claim 4 in particular). The US Patent '954 teaches that UV stessor is UV-c radiation (see column 8 in particular). Wherein the patient is human, and the aliquot of modified mammalian blood is the patient's own blood of volume from about 0.01-400 ml (column 9 and claim 2 in particular).

The WO ' 436 teaches a method of treating an inflammatory disease including psoriasis disease in a mammalian patient comprises administering to the patient stressed mammalian blood cells (see the entire document, pages 1, 17, and 23 in particular) . The WO ' 436 teaches that stress blood cells have been extracting from the patient an aliquot of blood of volume, contacting the aliquot of blood, extracorporeally subject to at both oxidative conditions, ultraviolet radiation and heat stress simultaneously. (see overlapping pages 13-14 and 16-17 in particular). The WO ' 436 teaches that oxidative environment, such as a mixture of ozone, wherein an ozone content from about 1.0 to about 100 μg/ml and oxygen bubbled through the blood aliquot, from about 0.5 to 60 min (pages 14-15, in particular). The WO ' 436 teaches that the temperature stressor is in a range from about 40 to about 55° C (see page 14 in particular). The WO ' 436 teaches that UV stessor is UV-c radiation (see page 15 in particular). Wherein the patient is human (page 8, paragraph 3 in particular), and the aliquot of modified mammalian blood is the patient's own blood (page 12, paragraph 4 in particular), of volume from about 0.01-400 ml (pages 8, 13, in particular).

It is noted that US Patent '954 or WO'436 does not explicitly teach a process of increasing the expression of TGF-β1 from the cells in a mammalian patient, comprising administering to the patient an effective amount of stressed mammalian blood cells. However, said functional limitation would be inherent properties of the recited method , taught by US Patent '954 or by WO'436 because both the prior art and the instant claims administered the same treatment, i.e. stressed mammalian blood cells to the same patients. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02. Since the office does not have a laboratory to test the reference method it is applicant's burden to show that the reference method, comprising administering to te patient stressed mammalian blood cells , would not increase the expression of TGF-β1 as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

13. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by WO 00/06703.

The WO ' 703 teaches a method of treating immunological and inflammatory disorder in a mammalian patient comprises administering to the patient stressed mammalian blood cells (see the entire document Abstract in particular . The WO '703 teaches that stress blood cells have

been extracting from the patient an aliquot of blood of volume, contacting the aliquot of blood, extracorporeally subject to at both oxidative conditions, ultraviolet radiation and heat stress simultaneously. (see overlapping pages 5-6 and 7 in particular). The WO '703 teaches that oxidative environment, such as a mixture of ozone, wherein an ozone content from about 1 to about 100 μg/ml and oxygen bubbled through the blood aliquot, from about 0.5 to 60 min (pages 7 and 9 , in particular). The WO '703 teaches that the temperature stressor is in a range from about 40 to about 55° C (see pages 8 and 11 in particular). The WO '703 teaches that UV stessor is UV-c radiation (see page 8 in particular). Wherein the patient is human and the aliquot of modified mammalian blood is the patient's own blood , of volume from about 0.1-500 ml (page 7, in particular).

It is noted that WO ' 703 does not explicitly teach a process of increasing the expression of TGF-β1 from the cells in a mammalian patient, comprising administering to the patient an effective amount of stressed mammalian blood cells. However, said functional limitation would be inherent properties of the recited method , taught by WO' 703 because both the prior art and the instant claims administered the same treatment, i.e. stressed mammalian blood cells to the same patients. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02. Since the office does not have a laboratory to test the reference method it is applicant's burden to show that the reference method, comprising administering to te patient stressed mammalian blood cells , would not increase the expression of TGF-β1 as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The references teaching anticipates the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

13. Claims 1 -19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/07436 or U.S. Patent No. 5,980,954 or WO00/06703 each in view of Zhou et al (IDS), known fact disclosed in the Specification on page 2, line 1-10 and optionally Stedman's Medical Dictionary, 27 th Edition.

The teaching of U.S. Patent No. 5,980,954 , WO 98/07436 , and WO00/06703 have been discussed, supra

US Patent '954 or WO'436, or WO 703 do not explicitly teach the process of treating ulcers in a mammalian comprising administering to said patients an effective amount of stressed mammalian blood.

Zhou et al., teaches that promoting expression of the cytokine TGF-β1 in a mammals will also promote the healing of ulcer (see entire document, Abstract in particular).

The known fact disclosed in the Specification on page 2, line 1-10 teaches that cytokines, including TGF-β1 play a key role in the immune response, including autoimmune response and inflammatory diseases.

Stedman's Medical Dictionary teaches that ulcer is one type of an inflammatory disease and often suppurating lesion on the skin or an internal mucous surface .

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Zhou et al., , known fact and Stedman's Medical Dictionary to those of US Patent '954 or WO'436, or WO 703 to obtain a claimed method for treating ulcers in a mammalian comprising administering to said patients an effective amount of stressed mammalian blood.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because promoting expression of the cytokine TGF-β1 in a mammals will also promote the healing of ulcer as taught by Zhou et al., and TGF-β1 play a key role in the immune response, including autoimmune response and inflammatory diseases as taught by the known fact and ulcers is one type of an inflammatory disease as taught by Stedman's Medical Dictionary. Thus the method for treatment of an inflammatory diseases, comprising administering a stressed blood cells that would result in promoting expression of the cytokine TGF-β1 in a mammals, as taught by WO 98/07463 , U.S. Patent No. 5,980,954 or WO00/06703 can be used for treating ulcers. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 7, 10, 16 and 19 are included because the claimed functional limitation would be an obvious properties of the referenced method for treating inflammation in a mammalian patient comprises administering to the patient stressed mammalian blood cells. The claimed blood volume from about 0.1-100 ml is within the reference ranges of 0.01-400 ml taught by WO '436 and US Patent '954 and 0.1 – 500 ml taught by WO'703. The claimed ozone content from about 0.1 to about 100 μg/ml is within the reference ranges of 1.0-100μg/ml, taught by WO'703 and WO'436 and 05-100 μg/ml taught by US Patent '954. Therefore, the claimed invention is an obvious variation of the reference teachings, absent a showing of unobvious differences. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-18 of copending Application No. 10002,634 in view of Zhou et al and Patarca et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 12-18 of copending Application No. 10002,634 recites a method for treatment of chronic fatigue syndrome comprising administering to said patients an effective amount of stressed mammalian blood.

Claims 12-18 of copending Application No. 10002,634 do not explicitly recites the process of treating ulcers in a mammalian comprising administering to said patients an effective amount of stressed mammalian blood.

Zhou et al., teaches that promoting expression of the cytokine TGF-β1 in a mammals will also promote the healing of ulcer (see entire document, Abstract in particular).

Patarca et al., teaches that Chronic Fatigue Syndrome is inflammatory and immune disorder associated with TGF-β1 deficiency (see entire document, Abstract and page 79 in particular).

Thus it would have been obvious to a person of ordinary skill in the art at the time the invention was made that method of treating chronic fatigue syndrome, comprising administering to said patients an effective amount of stressed mammalian blood, taught by Copending Application No. 10002,634 can be used to treat ulcers because both diseases are inflammatory and immune disorders associated with TGF-β1 deficiency as taught by Zhou et al and Patarca et al.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. No claim is allowed.

16. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
November 15, 2004

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